Introduction

Transplantation is the procedure involving the removal of a bodily organ or tissue from one person, and the insertion of that organ or tissue into another person to replace a damaged organ or tissue.

Definition of Terms:
Allograft – transplant from one individual to another (synonymous with homograft)
Hereotopic graft – transplant placed in a site different than the organ's normal location
Orthotopic graft – transplant placed in its normal anatomical site
Syngeneic graft (isograft) – transplant between identical twins
Xenograft – transplant between different species

Organ transplantation is now well established as an effective treatment for selected patients with end-stage organ failure. Transplantation of the kidney, liver, pancreas, heart, and lungs are all routine procedures, and transplantation of the small intestine is becoming more widely practiced. Currently, transplant activity is limited only by the shortage of cadaveric organs.

The following policy contains the minimal criteria for solid organ transplants. Additional justification may be required at the discretion of the Division of Medical Assistance Hospital Consultant staff.

1.0 Definition of the Procedure

Heart transplantation is the surgical excision of a heart and the main arteries from a human, brain-dead donor, with subsequent implantation into a recipient who has had their heart surgically removed.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

2.2 Special Provisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. § 1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at http://www.dhhs.state.nc.us/dma/prov.htm.

3.0 When the Procedure is Covered

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

The N.C. Medicaid program covers heart transplantation for patients with end-stage heart disease of any etiology who meet the following criteria:

3.1 Adults (not all inclusive)

1. Symptomatic heart failure (NYHA Class III-IV) refractory to medical therapy
   a. peak VO2 less than 11ml/kg/min (or % predicted peak VO2 less than 45%)
   b. peak VO2 =12-16 ml/kg/min (or % predicted peak VO2 =45-60%) considered probable indication
2. Refractory life-threatening arrhythmias
   a. recurrent symptomatic life-threatening ventricular arrhythmias, which cannot be controlled with all available medical or surgical therapy
   b. prolonged episodes of electromechanical disassociation following AICD conversion of VT or VF to sinus rhythm.
3. Unstable angina with a high risk of myocardial infarction in revascularization is not an option
4. Congenital anomalies not amenable to repair or ventricular failure after prior palliative or reconstructive procedures

3.2 Pediatric (not all inclusive)

1. Hypoplastic left heart syndrome, or other lethal congenital heart disease for which there is no standardized treatment.
2. End-stage cardiomyopathy (including failed palliative surgery)

4.0 When the Procedure is Not Covered

Heart transplantation is not covered when the medical necessity criteria listed in **Section 3.0** are not met. Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

The N.C. Medicaid program does not cover heart transplantation when one of the following conditions exists (not all inclusive):

4.1 Adult

1. advanced age (generally over 65)
2. elevated and irreversible pulmonary vascular resistance (> six woods units, and not responsive to pharmacological manipulation)
3. history of malignancy (except certain malignancies considered cure > five years)
4. insulin dependent diabetes, with evidence of organ complications such as:
   - retinopathy
   - neuropathy
   - nephropathy
   - peripheral **and** cerebrovascular disease
5. severe peripheral vascular disease
6. HIV positive
7. smoking/tobacco use – must be abstinent for minimum of one year

8. obesity greater than 130% of ideal body weight
9. chronic bronchitis or chronic obstructive pulmonary disease
10. psychosocial history that would limit ability to comply with medical care pre and post transplant
11. irreversible hepatic function
12. systemic illness/disease that would limit life expectancy or compromise recovery from cardiac transplantation
13. current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable
14. heart transplants that require concurrent coronary artery bypass graft surgery
15. history of or active substance abuse – must have documentation of substance abuse program completion plus six months of negative sequential random drug screens

    Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.

4.2 Pediatric

1. unstable metabolic and hemodynamic status despite receiving supportive measures
2. active clinical infection
3. significant neurological deficit
4. significant renal malformations in infants under one year
5. chromosomal abnormalities or syndromes that would limit survival or benefit from transplantation.
6. history of or active substance abuse – must have documentation of substance abuse program completion plus six months of negative sequential random drug screens

   Note: To satisfy the requirement for sequential testing as designated in this policy, DMA must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.
7. psychosocial history that would limit ability to comply with medical care pre and post transplant
8. current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable

4.3 Donors

Living donor expenses **are not applicable** for a heart transplant.

5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

All procedures must be prior approved by the Division of Medical Assistance.

6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

FDA approved procedures, products, and devices for implantation must be utilized.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of the procedure.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1985

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.

Attachment A
Claims Related Information

Reimbursement requires compliance with all Medicaid guidelines including obtaining appropriate referrals for recipients enrolled in the Medicaid Managed Care programs.

A. Claim Type

1. Physicians bill professional services on the CMS-1500 claim form.
2. Hospitals bill for services on the UB-92 claim form.

B. Diagnosis Codes that Support Medical Necessity

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

C. Procedure Codes

Codes that are covered include: 33945

D. Providers must bill their usual and customary charges.